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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,537	04/16/2001	Carl R. Merril	PNC-004	5407

7590 01/13/2004

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,537	MERRIL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6-15 and 19-29* is/are rejected.

7)☐ Claim(s) *5 and 16-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Duplicate Claim Warning

Applicant is advised that should claim 1 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4,6,8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4,6,8 recites the limitation "the dosage" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,7,9,10,15,19,20,23,24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pocchiari et al (Hormone Research, 19991, vol. 35 no. 3-4, pp. 161-6).

Pocchiari teaches a method of treating prion disease (scrapie) in human comprising administering a prion protein denaturing effective agent (6 M urea) to the human. It is inherent that the administration of the 6 M urea would induce hyperthermia. See abstract.

Claims 1-3,9,10,13-15,19-21,23,24,27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Manuelidis et al (Proceeding of the National Academy of Sciences of USA, 1995, vol. 92 no. 11 pp. 5124-8). Manuelidis teaches a method of treating prion diseases: scrapie in sheep; and Creutzfeldt-Jakob (CJD) disease in human, comprising administering a prion protein denaturing effective agent (guanidine hydrochloride) to the mammals. It is inherent that the administration of the guanidine hydrochloride would induce hyperthermia. See abstract.

Claims 1,2,7-15,19,20,22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Madec et al (Archives of Virology, 1997, vol. 142 no. 8, pp. 1603-1612). Madec teaches a method of treating prion diseases: scrapie in sheep; bovine spongiform encephalopathy in cows; and Creutzfeldt-Jakob disease in human, comprising administering a prion protein denaturing effective agent (1-7 M urea and 0.25-3 M guanidine thiocynate) to the mammals. It is inherent that the administration of the urea and guanidine thiocyanate would induce hyperthermia. See abstract.

Claims 1,2,9,10,15,19,20,23,24 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldin et al (US 5403861; 4/4/95). Goldin teaches a method of treating prion disease (insomnia) in human comprising administering a prion protein denaturing effective agent (guanidine salt) to the human. It is inherent that the administration of the

guanidine would induce hyperthermia. See abstract, column 8 line 64 – column 9 line 20.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,2,9,10,13-15,19,20,23,24,27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Garssen et al (WO 0048003; 8/17/00). Garssen teaches a method of treating prion diseases: scrapie; spongiform encephalopathy; fatal familial insomnia; kuru; Gerstmann-Straussler-Scheinker disease (GSS) and CJD in human and animals, comprising administering a prion protein denaturing effective agent (1-7 M urea and 0.25-3 M guanidine thiocynate) to the mammals. It is inherent that the administration of the urea and guanidine thiocyanate would induce hyperthermia.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3,7,9-11,13-15,19-21,23,24,27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (US 2002/0132268; 9/19/02). Chang teaches a method of treating prion diseases: scrapie in sheep; CJD in human; GSS in human; familial insomnia in human; and kuru in human, comprising administering a prion protein denaturing effective agent (urea and guanidine chloride) to the mammals. It is inherent

that the administration of the urea and guanidine chloride would induce hyperthermia. See abstract, page 8 paragraphe 107, claims 48-50.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pocchairi as applied to claims 1,2,7,9,10,15,19,20,23,24. See Pocchairi 35 USC 102(b) rejection above. Pocchairi teaches all that is recited in claim 8 except for the invention comprising the instant amount of urea. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of urea. One would have been motivated to do this in order to make an invention that would have been most effective in treating prion disease.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manuelidis as applied to claims 1-3, 9,10,13-15,19-21,23,24,27-29. See Manuelidis 35 USC 102(b) rejection above. Manuelidis teaches all that is recited in claim 4 except for the invention comprising the instant amount of guanidine hydrochloride. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of guanidine hydrochloride. One would have been motivated to do this in order to make an invention that would have been most effective in treating prion disease.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madec as applied to claims 1,2, 7-15,19,22-29. See Madec 35 USC 102(b) rejection above. Madec teaches all that is recited in claim 4 except for the invention comprising the instant amount of guanidine thiocyanate. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of guanidine thiocyanate. One would have been motivated to do this in order to make an invention that would have been most effective in treating prion disease.

Claims 4,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang as applied to claims 1-3, 7,9-11,13-15,19-21,23,24,27-29. See Chang 35 USC 102(e) rejection above. Chang teaches all that is recited in claims 4,8 except for the invention comprising the instant amounts of guanidine chloride and urea. It would have been obvious to one having ordinary skill in the art to determine the optimum amounts of guanidine chloride and urea. One would have been motivated to do this in order to make an invention that would have been most effective in treating prion disease.

Claim Objection / Election Status

Claims 5,16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant method comprising potassium iodide; microwave energy; pyrogenic material. The elected method of treating Scrapie is not allowable. See art rejections above.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

ALTON N. PRYOR
PRIMARY EXAMINER

Alton Pryor
Primary Examiner
AU 1616